UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
WASHINGTON, D.C. 20460

March 7, 2001

MEMORANDUM

SUBJECT: **Sodium Acifluorfen:** Revised Occupational and Residential Non-Cancer and Cancer Exposure and Risk Assessments for the Reregistration Eligibility Decision (RED) Document [Case # 819467, PC Code 114402, DP Barcode D252558]

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Attached is the Revised Occupational and Residential Exposure and Risk Assessment document for the Sodium Acifluorfen HED RED Chapter. The assessment was revised to include an exposure monitoring study, a DFR study, a new Q_1* for cancer risk and new transfer coefficients for post application exposure. The assessment reflects current HED policy.

Active EPA Reg #: 4-433, 241-321, 7969-076, 7969-077, 7969-079, 7969-080, 7969-087, 7969-168, 7969-179, 71995-003

EPA MRID #: 423615-01, 440911-01, 440911-02

PHED: Yes, Version 1.1 (August 1998, Surrogate Table)

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1. Occupational and Residential Executive Summary for Sodium Acifluorfen

Summary Description for Sodium Acifluorfen:

Sodium Acifluorfen (Sodium 5-[2-chloro-4-(trifluoromethyl) phenoxy] -2-nitrobenzoate; CAS # 62476-59-9) is the salt of a diphenyl ether and is used as contact herbicide. For the purposes of this assessment this chemical shall be referred to as acifluorfen. According to the Sodium Acifluorfen Use Closure Memo (dated 11/01/99) there are eight registered, supported products of acifluorfen intended for agricultural use and two products for residential use. The agricultural products which are formulated as an emulsifiable concentrate (7 - 21% acifluorfen) are used for post emergence weed control in peanut, rice and soybean fields. The residential product (0.12% acifluorfen) is a ready to use trigger sprayer for spot treatments to kill weeds in driveways, sidewalks, patios and around trees.

Several acifluorfen products also contain other registered herbicides such as: bentazon, sodium salt; glyphosate, isopropylamine salt; and imazaquin, sodium salt. These herbicides are not addressed in this risk assessment. In addition, sodium acifluorfen is a degradate of another registered pesticide, lactofen. Potential exposures from contact with sodium acifluorfen following the application of lactofen products is not addressed in this risk assessment.

As full coverage of a crop is required for acifluorfen to be effective as a contact herbicide, applications to peanuts, rice and soybeans are limited to the use of aerial and groundboom equipment. Spray additives are required for the agricultural products and include non-ionic surfactants, urea ammonium nitrate and crop oil.

Based upon available pesticide survey usage information for the years 1987-1997, the Biological and Economic Effects Division (BEAD) of EPA estimates that total annual domestic usage for applications of acifluorfen is approximately 1.5 million pounds active ingredient (ai) for about 6 million acres treated. Acifluorfen has its largest markets, in terms of total pounds active ingredient, allocated to soybeans (94%), peanuts (4%), and rice (2%). Most of this usage is in Arkansas, Mississippi, Illinois, Missouri, Indiana, North Carolina, Virginia, Texas and Alabama. Crops with a high percentage of the total U.S. planted acres treated include: soybeans (90%), peanuts (3%) and rice (2%).

Sodium Acifluorfen Toxicology Endpoints:

The following endpoints were used in this assessment:

$NOAEL_{Short\text{-}term,dermal}$ and $NOAEL_{Intermediate\text{-}term,dermal}$ = 20 mg/kg/day; dermal absorption = 20%
$NOAEL_{Short\text{-}term,inhalation}$ and $NOAEL_{Intermediate\text{-}term,inhalation}$ = 20 mg/kg/day; inhalation absorption = 100%
$Q_1^* = 5.3 \times 10^{-2}$ $(mg/kg/day)^{-1}$

HIARC and the FQPA SFC determined that MOEs greater than 100 do not exceed the

Agency's level of concern for acifluorfen occupational non-cancer exposures. MOEs greater than 1000 do not exceed the Agency's level of concern for acifluorfen residential non-cancer exposures. Occupational cancer risks below 1.0×10^{-4} do not exceed the Agency's level of concern while residential cancer risks do not exceed the Agency's level of concern when they are below 1.0×10^{-6}.

Private grower and Professional Pesticide Applicator Non-Cancer and Cancer Risk Assessments:

HED has determined that private growers and professional pesticide applicators (i.e. mixers, loaders, applicators, flaggers) are likely to be exposed during acifluorfen use and that these uses would result in short/intermediate term exposures. Because the acifluorfen products are typically applied only one or two times per year, long-term or chronic exposures (i.e., daily exposures which occur for a minimum of several months) are not expected. The anticipated use patterns and current labeling indicate six exposure scenarios based upon the types of equipment that potentially can be used to make acifluorfen applications.

One chemical-specific exposure and biomonitoring study (MRID 423615-01) was submitted by BASF in support of the reregistration of acifluorfen. This study monitored the dermal exposure, inhalation exposure and urinary excretion of private grower owner mixer/loader/applicators who used Blazer for weed control in Wisconsin, New York and Maryland/Delaware. The blazer was applied to soybean fields at a rate of 0.50 lbs ai/acre using groundboom sprayers pulled by open cab tractors. The workers wore single layer PPE without respirators during mixing and baseline PPE during application. Dermal exposure was measured using 10 x 10 cm gauze patches, hand exposure was measured using bag washes, and inhalation exposure was measured in the breathing zone using personal air pumps with air sampling tubes. Biomonitoring was accomplished by measuring acifluorfen residues and metabolites in 24 hour urine samples collected by each test subject for several days before, during and after exposure.

This study was reviewed by the agency and parts of it were found to be acceptable. Most of the analytical dermal data was grade A or B except for the sun exposed dosimeter data which was rated grade C for low recovery. The inhalation data was rated as "low confidence" because the sampling tube did not include a component to capture the aerosol fraction of the herbicide spray. The urine data has severe limitations because the pharmacokinetics of acifluorfen was not well documented, many of the reported results were below the limit of quantification and there were only seven valid test subjects. For the above reasons, only the dermal and inhalation exposure data were used in this assessment. This data indicated that unit exposure values were 5 times higher than those predicted by the Pesticide Handlers Exposure Database (PHED), Version 1.1 (August 1998).

In addition to the submitted study, analyses for both private grower and professional short/intermediate term exposures were performed using PHED. Five mixer/loader, applicator, mixer/loader/applicator and flagger scenarios were evaluated.

The submitted data and calculations indicate that the MOEs for two exposure scenarios

(mixing/loading liquids for aerial application and mixing/loading liquids for groundboom application) are below 100 for the baseline level and exceed HED's level of concern. The MOEs for the remainder of the exposure scenarios are above 100 for baseline and higher levels of mitigation and therefore do not exceed HED's level of concern. The data input variables and calculations are included in Appendix B.

The calculations of private grower and professional acifluorfen applicators' cancer risks indicate that two scenarios (mix/load liquids for aerial application and mix/load liquids for groundboom application) exceed 1.0×10^{-4} at the baseline level. All of the other scenarios are below 1.0×10^{-4} at the baseline level and some are below 1.0×10^{-5} at the single layer PPE level. One of the scenarios (mix/load liquids for aerial application) for professional acifluorfen applicators exceeds 1.0×10^{-6} at the engineering control mitigation level. None of the scenarios for the private grower applicator exceed 1.0×10^{-6} at the engineering control level. The calculations and summary tables are included in Appendix B.

Post-Application Worker Non-Cancer and Cancer Risk Assessments:

The Agency has determined that workers may be exposed to acifluorfen during scouting, hand weeding and irrigating treated areas. Due to the frequency and duration of these exposures coupled with the dissipation of acifluorfen following applications, it was determined that these exposures would be short/intermediate term and would occur primarily by the dermal route. Inhalation exposures are not anticipated for post-application worker exposures, and the Agency currently has no policy/method for evaluating non-dietary ingestion by workers due to poor hygiene practices or smoking. As a result, only dermal exposures were evaluated in the post-application worker assessment. The Agency assumes that all harvesting of peanuts, rice and soybeans will be performed mechanically. In addition, the Agency assumes that transplanting by hand will not occur for these crops in the United States.

A study "Foliar Dislodgeable Residues of Blazer on Soybeans" (MRID 440911-01) was submitted by BASF in support of the reregistration of acifluorfen sodium. This study measured dislodgeable foliar residues following groundboom application of Blazer to control weeds in soybean fields in Indiana, Mississippi and Georgia. Two applications, 15 days apart, were made at each site. The amount applied was 0.125 lb ai/acre for the first application and 0.375 lb ai/acre for the second application. Three samples at each site were collected before and after each application then 1,3,5,7,10,14,21,28 and 35 days after the second application. Leaf disk samples were collected using Birkestrand leaf punches and were dislodged in an ivory soap solution. No acifluorfen sodium residue was detected prior to either the first or second application at any of the sites. The average acifluorfen sodium DFR (n=3) ranged from 0.25 ug/cm^2 in GA to 0.74 ug/cm^2 in MS. Regression analysis of the LN of the DFR levels vs. the days after treatment yielded a daily dissipation rate of 39% for the Indiana data (r = 0.97, n=18) and 79% for the Mississippi data (r = 0.99, n=9). The slope of the two data points for Georgia yielded a daily dissipation rate of 91%.

The DFR study was reviewed by the Agency and was found to be acceptable. The DFR data

for the Indiana and Mississippi sites were used for the calculations of Post Application exposures and risks. The Georgia data were not used because a rain event occurred less than one day after the second application. The current REI for acifluorfen is 48 hours based on acute eye irritation. The calculated REIs represent the duration in days which must elapse before the Agency would not have concern for a worker, wearing a long-sleeved shirt and long pants, to enter the treated area and perform specific tasks. Calculated REIs for each of these crops yielded MOEs greater than 100 on Day 0 which suggests that the current REIs are appropriate. In addition, none of the post-application cancer risks to private grower and professional workers is greater than 1.0×10^{-4} for day 0 exposures at typical acifluorfen application rates. Post-application worker non-cancer and cancer risks are found in Appendix C.

Residential Applicator Non-Cancer and Cancer Risk Assessments:

HED has determined that residential pesticide applicators are likely to be exposed to acifluorfen during one scenario (spot treat weeds in driveways, sidewalks, patios and around trees). The calculations of residential acifluorfen applicators' combined dermal and inhalation risks using PHED data indicate that the MOE of 4300 for this exposure scenario is greater than the target MOE of 1000 and does not exceed HED's level of concern. The target MOE is 1000 due to the FQPA safety factor for females 13-50 years of age. In addition, a cancer risk of 8.3×10^{-7} was calculated for this scenario. Cancer risks above 1.0×10^{-6} for the general population are generally of concern to HED. Residential applicator non-cancer and cancer risks are found in Appendix D. There are no concerns of post application residential exposure because residential uses are limited to spot treatments which do not include broadcast application to lawns (the label states that acifluorfen kills grass).

Incident Reports:

No incidents involving acifluorfen were found in the data sources consulted by the Health Effects Division.

Information and Data Needs:

Several areas of the risk assessment and characterization would improve with more information and data. Areas of information and data needs include:

- Additional dermal absorption data to refine the dermal absorption factor of 20% which was derived from a ten hour rat study done in 1986. This data is needed to determine if the use of a soap solution will significantly decrease the material remaining on the skin and if the material remaining on the skin after washing is available for absorption.
- Usage and exposure data for the residential use.

2. Background Information

This revised document is based upon the following referenced documents.

(1) Revised Sodium Salt of Acifluorfen (Tackle™, Blazer™) Quantitative Risk Assessment (Q1*); Author Lori L. Brunsman, SAB/HED/OPP (08/23/00) [HED Doc. No. 014296] .
(2) Acifluorfen - Report of Food Quality Protection Act Safety Factor Committee ; Author: Brenda Tarplee, (09/29/99) [HED Doc. No. 013764].
(3) Acifluorfen Hazard Identification And Review Committee Report; Author: Paul Chin, PhD, RRB1/HED/OPP; (04/07/99) [HED Doc. No. 013308].
(4) Review of Acifluorfen (Tackle (R)), Dermal Absorption Study, (2/11/86) [EPA Accession #260951]
(5) Acifluorfen: Review of Incident Reports; Authors: Jerome Blondell, PhD, and Monica Spann, MPH, CEB1/HED/OPP; Chapter directed to Kit Farwell, DVM, RRB1/HED/OPP (04/06/00).
(6) Acifluorfen labels.
(7) Acifluorfen Use Closure Memo; Author: Christina Scheltema, CRM for acifluorfen, SRRD/OPP; Memo directed to Acifluorfen Team (11/01/99).
(8) Draft Standard Operating Procedures for Residential Exposure Assessments. U.S. EPA. February 10, 1998.
(9) HED Science Advisory Council for Exposure, Policy 003.1, "Agricultural Default Transfer Coefficients" Health Effect Division, Office of Pesticide Programs. August, 1998.
(10) HED Science Advisory Council for Exposure, Policy.007, "Use of Values from the PHED Surrogate Table and Chemical-Specific Data." Health Effects Division, Office of Pesticide Programs. January, 1999.
(11) HED Science Advisory Council for Exposure, Policy.009, "Standard Values for Daily Acres Treated in Agriculture" Health Effects Division, Office of Pesticide Programs. July 2000.
(12) PHED Surrogate Exposure Guide, V1.1. Health Effects Division, Office of Pesticide Program. August, 1998."
(13) A Strategy for Assessing and Managing Occupational Exposures, 2nd edition, AIHA Press, 1998.

3. Occupational and Residential Exposure and Risk Characterization

Occupational and residential exposure and risk assessments are required for an active ingredient if: (1) certain toxicological criteria are triggered **and** (2) there is potential exposure to handlers (i.e., mixers, loaders, applicators, etc.) during use or to persons entering treated areas after application is completed. Sodium Acifluorfen (Sodium 5-[2-chloro-4-(trifluoromethyl) phenoxy] -2-nitrobenzoate; CAS # 62476-59-9) meets both criteria. Sodium Acifluorfen (referred to as Acifluorfen hereafter) is a diphenyl ether in acute toxicity categories II and III by the oral and dermal routes and acute toxicity category IV by the inhalation route. There is potential exposure to private grower and professional pesticide applicators from agricultural site

applications of acifluorfen. In addition, the general public may be exposed to acifluorfen when applying it in the residential environment.

Several of the acifluorfen products for agricultural use also contain other registered active ingredient herbicides such as bentazon, sodium salt; glyphosate, isopropylamine salt; and imazaquin, sodium salt. These ingredients are not addressed in this risk assessment. In addition, sodium acifluorfen is a degradate of another registered pesticide, lactofen. Potential occupational exposures from contact with sodium acifluorfen following the degradation of applied lactofen was addressed in the risk assessment for lactofen. Currently, lactofen is only formulated for agricultural uses and is not used in a residential setting.

3.a. Summary of Acifluorfen Use Patterns and Formulations

3.a.i. Acifluorfen Uses

Based upon the Sodium Acifluorfen Use Closure Memo (dated 11/01/99) which can be found in Appendix A of this document, there are registered, supported products of acifluorfen intended for both occupational and residential site applications. The registered agricultural uses include peanuts, rice and soybeans. Residential homeowners may use acifluorfen products as a ready to use trigger sprayer for the spot treatment of weeds. Other types of residential applications/uses are not permitted without additional review.

Based upon available pesticide survey usage information for the years 1987-1997, the Biological and Economic Effects Division (BEAD) of EPA estimates that total annual domestic usage for applications of acifluorfen is approximately 1.5 million pounds active ingredient (ai) for about 6 million acres treated. Acifluorfen has its largest markets, in terms of total pounds active ingredient, allocated to soybeans (94%), peanuts (4%), and rice (2%). Most of this usage is in Arkansas, Mississippi, Illinois, Missouri, Indiana, North Carolina, Virginia, Texas and Alabama. Crops with a high percentage of the total U.S. planted acres treated include: soybeans (90%), peanuts (3%) and rice (2%).

3.a.ii. Mode of Action and Targets Controlled

Acifluorfen is used for selective postemergence control of certain broadleaf weeds and grasses. It is a contact herbicide, therefore, weeds must be thoroughly covered with spray.

3.a.iii. Formulation Types and Percent Active Ingredient

According to EPA OPP REFS label tracking system, there are currently 9 active products of acifluorfen manufactured. A total of 46 active and non-active acifluorfen products are produced by 10 companies for 14 different types of use sites to control 222 pest species. Acifluorfen is formulated for agricultural uses as an emulsifiable liquid concentrate which contains 6.8 to 21.4% active ingredient (ai), and for residential uses as a liquid ready-to-use (RTU) trigger sprayer

product which contains 0.12% ai.

3.a.iv. Maximum Application Rates, Timing and Frequency of Applications

The Sodium Acifluorfen Use Closure Memo specifies the maximum and typical (or average) acifluorfen application rates for agricultural uses. These rates are given in Table 1. Typically one or two applications are made early in the growing season to kill weeds less than 4 inches tall. In the case of Blazer, for example, applications of 0.125 lbs ai/acre and 0.375 lbs ai/acre are made 15 days apart to reach the maximum seasonal application rate of 0.5 lbs ai/acre/season.

Two residential use products: (1) Ortho Kleeraway Grass and Weed Killer and (2) Kleenup Grass and Weed Killer are listed in the REFS system. These products are packaged in 24 ounce to 1 gallon containers with built in trigger sprayers and are intended for spot treatment of weeds on driveways, sidewalks, patios and around trees. More recent information obtained from www.ortho.com indicates that Kleeraway Grass and Weed Killer currently does not contain acifluorfen. Residential use product information is given in Table 2.

Table 1 - Application Rates for Acifluorfen Agricultural Products

Product	Crop	Maximum Application Rate Per Application (lbs ai/Acre)	Typical Rate per Acre per Season(lbs ai)	Maximum Rate per Acre per Season(lbs ai)
Blazer	Peanuts	0.375	0.250	0.500
Storm	Peanuts	0.250	0.250	0.500
Blazer	Rice	0.250	0.125	0.250
Storm	Rice	0.250	0.250	0.250
Blazer	Soybeans	0.375	0.188	0.500
Status	Soybeans	0.375	0.188	0.500
Storm	Soybeans	0.250	0.250	0.500
Conclude Xtra B	Soybeans	0.250	0.250	0.250
Galaxy	Soybeans	0.250	0.168	0.250
Sceptor OT	Soybeans	0.250	0.250	0.500
Manifest	Soybeans	0.168	0.168	0.168
Conclude Ultra B	Soybeans	0.158	0.158	0.158

Table 2 - Residential Use Product Information for Acifluorfen		
Product/Company	**Use**	**Formulation and Application Method**
Ortho Kleeraway Grass and Weed Killer/ Monsanto	Spot treatment of weeds on driveways, sidewalks, patios and around trees	Ready to use liquid containing 0.12% Acifluorfen. Applied with a built in trigger sprayer
Kleenup Grass and Weed Killer/ Bonide		

3.a.v. Methods and Types of Equipment for Mixing, Loading, and Application

Acifluorfen is applied using aerial and groundboom spray equipment to ensure adequate coverage of the target weeds.

3.b. Occupational and Residential Exposure and Risk Assessments

The Agency has determined that there is potential for exposure in occupational settings from handling acifluorfen products during the application process (i.e., mixer/loader, applicator, and flagger) and from entering previously treated areas. In addition, the Agency has determined that there is potential for residential applicator exposure while applying acifluorfen products in residential environments to kill weeds. As a result, risk assessments have been completed for private grower and professional pesticide applicator scenarios, worker post-application scenarios, and residential applicator scenarios.

3.b.i. Endpoints and Calculations Used in the Exposure and Risk Assessments

The toxicological endpoints that were used to complete occupational and residential exposure assessments are summarized in Tables 3 and 4. These endpoints were selected from animal studies by the Health Effects Division Hazard Identification Assessment Review Committee (HEDs HIARC) and are discussed in detail in the HIARC document (HED Document #013308 of 4/7/99). The Food Quality Protection Act (FQPA) safety factor of 10 was retained for short- and intermediate-term dermal and inhalation exposures to most sensitive residential subgroup (females 13-50 years of age). A FQPA safety factor of 3 was assigned for chronic residential exposures to the subgroup of females 13-50 years of age. Please note that intermediate-term and chronic residential exposures are not anticipated.

Table 3. Acute Toxicity Categories for Sodium Acifluorfen.		
Test	**Results**	**Toxicity Category**
Acute Oral Toxicity	LD_{50} = 1540 mg/kg/day (rats) LD_{50} = 186 mg/kg/day (dogs)	III II
Acute Dermal Toxicity	LD_{50} > 2000 mg/kg/day (rabbits)	III
Acute Inhalation Toxicity	LC_{50} > 6.9 mg/L	IV
Acute Eye Irritation	Severe eye irritant	I
Acute Dermal Irritation	Moderate dermal irritant	II
Skin Sensitization	Not a skin sensitizer	----

Table 4. Toxicology Endpoints for Sodium Acifluorfen				
Test	**Study**	**Dose**	**Endpoint**	**UF**
Dermal – Short-Term and Intermediate-Term	Developmental (Rat)	NOAEL = 20 mg/kg/day (Dermal absorption rate = 20% of oral absorption)	Decreased fetal weight and increased incidences of dilated lateral ventricles of the brain	100 for occupational and 1000 for residential exposures
Inhalation -- Short-Term and Intermediate-Term	Developmental (Rat)	NOAEL = 20 mg/kg/day (Inhalation absorption rate =100% of oral absorption)	Decreased fetal weight and increased incidences of dilated lateral ventricles of the brain	100 for occupational and 1000 for residential exposures
Cancer (dermal and inhalation)	Cancer (mice)	$Q_1^* = 5.3 \times 10^{-2}$ (mg/kg/day)$^{-1}$	Liver tumors (adenomas, carcinomas, and adenomas /carcinomas combined) and stomach tumors (papillomas) in both sexes of mice	

NOAEL = No Observable Adverse Effect Level and UF = Uncertainty Factor

Exposure and Risk Equations for Occupational and Residential Handlers

Daily dermal and inhalation exposures, daily doses, and risks are calculated as described below. These calculations are used for private grower, professional and residential pesticide handlers and applicators. The first step is to calculate daily dermal and inhalation exposures.

Daily dermal exposure is calculated:

Daily dermal exposure = Unit exposure x Application rate x Area Treated
(mg/day) (mg/lb ai) (lb ai/acre) (acres/day)

Where:

Daily dermal exposure = amount deposited on the surface of the skin that is available for dermal absorption, also referred to as potential dose (mg/day);
Unit exposure = normalized exposure value (mg exposure per pound ai handled) derived from chemical specific study data or from the PHED Surrogate Exposure Table
Application rate = normalized application rate based on a logical unit treatment such as acres, a maximum value is generally used (lb ai/acre); and
Area treated = normalized application area such as acres/day.

[Note: (lb ai/acre) and (A/day) are replaced, respectively, with (lb ai/gal) and (gal/day) when appropriate]

Daily inhalation exposure is calculated:

Daily inhalation exposure = [Unit exposure x Application rate x Area Treated] / Conversion Factor
(mg/day) (ug/lb ai handled) x (lb ai/acre) x (acres/day) (1 mg/1000 ug)

Where:

Daily inhalation exposure = amount available for absorption, also referred to as potential dose (mg/day);
Unit exposure = normalized exposure value (μg/lb ai handled) derived from study data or PHED;
Application rate = same as for dermal exposure (lb ai/acre); and
Daily treatment = same as for dermal exposure (acres/day).

Daily dermal and inhalation doses are then calculated by normalizing the daily dermal and inhalation exposures by body weight. For private grower and professional pesticide applicators using acifluorfen, a body weight of 60 kg (adult female body weight) was used for all exposure scenarios because the effects observed in the toxicological studies were of concern for females 13-50 years of age.

Daily inhalation exposure levels were calculated for inclusion into the PHED surrogate exposure tables and presented as (μg/lb ai) based on a human inhalation rate of 29 L/minute and an 8-hour working day. The dermal and inhalation doses for short- and intermediate-term scenarios were calculated using the following equation.

Absorbed Daily Dose is calculated:

Absorbed daily dermal or inhalation dose = (Daily dermal or inhalation exposure x absorption factor) / body weight
(mg/kg/day) (mg/day) (unitless) (kg)

[Note: 60 kg human; calculates a potential biologically-available dose resulting from dermal or inhalation exposure; an absorption factor of 0.20 was used for dermal exposures and 1.0 for inhalation exposures.]

Because exposures from the dermal and inhalation routes have the same toxicological effects, a combined absorbed daily dose can be calculated. Once the combined absorbed daily doses are calculated, the combined Margins of Exposure (MOEs) can be calculated.

Combined Absorbed Daily Dose is calculated:

Combined Dose (mg/kg/day) = Absorbed dermal dose (mg/kg/day) + Absorbed inhalation dose (mg/kg/day)

Combined Margin of Exposure is calculated:

Combined MOE (unitless) = NOAEL (mg/kg/day) / Combined Dose (mg/kg/day)

Combined MOEs greater than 100 for private grower and professional pesticide applicator exposures to acifluorfen do not exceed the Agency's level of concern.

The HED Cancer Peer Review Committee determined sodium acifluorfen to be a B2 carcinogen (probable human carcinogen) and calculated a potency value or Q_1* of 5.3 x 10^{-2} $(mg/kg/day)^{-1}$. Cancer risks of less than 1.0 X 10^{-4} (one in ten thousand) for the occupational population and less than 1 x 10^{-6} (one in a million) for the general population do not exceed the Agency's level of concern. The Agency closely examines occupational cancer risks in the 1 x 10^{-4} to 1 x 10^{-6} range and seeks ways to reduce occupational cancer risks to the greatest extent feasible, preferably 10^{-6} or less. When this approach is used, the implicit assumptions are that any exposure will lead to some level of risk and that risk is directly and linearly proportional to exposure, regardless of the dosing schedule.

Average daily doses for cancer risk assessments are calculated as described above for non-cancer risk assessment except that the average application rates are used instead or the maximum rates. Once the Average daily dose is calculated, a Lifetime Average Daily Dose (LADD) can be calculated. To obtain the cancer risk associated with a specific exposure scenario, the LADD is multiplied by Q_1*.

Lifetime Average Daily Dose (LADD) is calculated:

LADD (mg/kg/day) = Combined Dose (mg/kg/day) x (# days worked/365 days per year) x (35 years worked/70 year lifetime)

[Note: the # days worked by professional applicators is typically 10 times that of private growers.]

Cancer Risk is calculated: Cancer Risk = LADD (mg/kg/day) x Q_1^* $(mg/kg/day)^{-1}$

Exposure and Risk Calculations for Post-Application Worker Assessments

The Agency is concerned about potential occupational post-application exposure to acifluorfen from entering treated agricultural fields for scouting, hand weeding and irrigating. The Agency anticipates that all harvesting of peanuts, rice and soybeans will be performed mechanically and will request confirmatory data regarding this assumption. In addition, the Agency assumes that transplanting by hand will not occur for these crops in the United States.

The calculations used to estimate daily dermal dose and MOE for the dermal post-application scenarios are similar to those described previously for the private grower and professional pesticide applicator scenarios. The only significant differences are: (1) the manner in which daily

dermal dose is calculated using a transfer coefficient, transferable residues, and accounting for the dissipation of acifluorfen over time and (2) inhalation exposures were not calculated for the post-application scenarios because inhalation exposures have been shown to account for a negligible percentage of the overall body burden. This is particularly true for Acifluorfen which has a very low vapor pressure (0.01mPA at 20 C).

The following equation was used to calculate dermal doses for acifluorfen on each post-application exposure day after application.

Post-Application Dermal dose is calculated:

Dermal dose = (TR(t) x TC x DA x conversion factor x # hours worked/day) / body weight (kg)
(mg/kg/day) (ug/cm^2)

Where:

Dermal dose (t) = dermal dose attributable to exposure at time (t) when engaged in a specific mechanical activity or job function (mg/kg/day);
Transferable residue (TR) = transferable residue or foliar dislodgeable residue at time (t) [$\mu g/cm^2$];
TC = transfer coefficient or measure of the relationship of exposure to transferable residue concentrations while engaged in a specific mechanical activity or job function;
DA = dermal absorption factor = 0.2
Hours worked/day = exposure duration or hours engaged in specific mechanical activity (hrs/day); and
Body weight = body weight (kg).

[Note: no chemical-specific transfer coefficients were available; standard transfer coefficients are presented later in text;

Once the post-application dermal doses are calculated, the dermal Margins of Exposure (MOEs) can be calculated. Dermal MOEs greater than 100 for post-application worker exposures to acifluorfen do not exceed the Agency's level of concern.

Margin of Exposure is calculated:

MOE (unitless) = NOAEL (mg/kg/day) / Absorbed Dermal Dose (mg/kg/day)

3.b.ii. Risk Assessment Assumptions and Factors

The following assumptions and factors were used in order to complete the exposure and risk assessments contained in this document:

- The average work day was 8 hours.
- The daily acreages treated were taken from EPA Science Advisory Council for Exposure Policy #9 "Standard Values for Daily Acres Treated in Agriculture," Revised July 5, 2000.

- Maximum application rates were used to evaluate non-cancer occupational risk.
- Average application rates were used to evaluate cancer occupational risk.
- Unit exposure values were calculated in PHED using the following protection factors for PPE: double layer of clothing = 50% PF for dermal exposure to the body, chemically resistant gloves 90% PF for dermal exposure to the hands, dust mask 80% PF for inhalation exposure and half face cartridge respirator = 90% PF for inhalation. Engineering controls are assigned a protection factor of 90% to 98% depending upon the type of engineering controls selected.
- A body weight of 60 kg was assumed for all non-cancer scenarios because the non-cancer endpoint of concern relates to females 13-50 years of age.
- A body weight of 70 kg was assumed for all cancer scenarios.
- For the non-cancer occupational exposure assessments of acifluorfen, a Margin of Exposure (MOE) of 100 was assigned by HIARC.
- For the residential applicator assessment of acifluorfen, a MOE of 1000 was assigned for the subgroup of females 13-50 years of age by FQPA SFC; a body weight of 60 kg was assumed for females in this subgroup.

3.b.iii. Occupational Handler Exposure Data Sources

Submitted Studies

The following chemical specific occupational handler exposure study was submitted by BASF in support of the reregistration of acifluorfen, and was judged to be appropriate for use in the HED occupational exposure/risk assessments.

***EPA MRID 42361501**: Baughner, D. (1992) **Passive Dermal Dosimetry and Biological Monitoring of Exposure of Mixer/Loaders and Applicators to Blazer (Acifluorfen-Sodium)** Unpublished study prepared by Orius Associates**;**

*Memorandum: Review of Acifluorfen (Blazer) Groundboom Mixer/Loader/Applicator Exposure and Biomonitoring Study: D270365; dated 2/7/01 by Timothy C. Dole

The purpose of this study was to monitor worker exposure and urinary excretion during the groundboom application of acifluorfen - sodium to soybeans to control weeds. This study was submitted by BASF to support the registration of acifluorfen-sodium. The formulation used in this study was Blazer Herbicide, a 2 lb/gallon soluble concentrate formulation of acifluorfen-sodium. Citowett Plus nonionic surfactant was used an adjuvant.

This study was conducted at three farms in Wisconsin, two farms on the Maryland/Delaware peninsula and two farms in New York. Two or three workers were monitored on each farm for a total of 10 workers. The weather conditions were well documented and were typically hot and

humid. The worker clothing and PPE usage was well documented and workers generally wore long sleeve shirts with or without short sleeve T-shirts underneath; and long pants or cotton long zip front coveralls. Solvex nitrile gloves, chemical goggles and rubber boots were generally worn during mixing/loading. Gloves were not worn during application except to adjust nozzles and make repairs. The spray mixture was mixed by the workers by manually pouring the Blazer and Citowett Plus additive into the tanks and diluting with water from a hose. It was observed that the additive caused excessive foaming. Blazer was applied at a rate of 0.54 lb. ai/acre with a dilution rate of 17-27 gallons of water per acre. Two to eight tank-loads of finished spray were handled per replicate and an average of 9 acres per hour was treated. The spray was applied by one saddle mounted and nine tractor pulled ground booms. Two of the tractors had semi-enclosed cabs with the back and/or side windows open while the remaining tractors did not have cabs.

Dermal exposure was measured by collecting ten half day and five full day dermal sample sets for a total of 15 replicates. Each sample set consisted of thirteen glassine-backed cotton gauze patches that covered approximately five percent of the workers body. The author stated that "whole body dosimeters were not used: the interception of residues available for dermal absorption would have confounded the biological monitoring." Three of these patches were attached to the outer surface of the workers clothing at the top of the baseball cap, back of the neck and next to the chest "V." The other ten patches were attached to the worker's skin using surgical tape at the shoulders, mid-forearms, front thighs, shins, back and chest. The patches were removed at the end of the sampling period by cutting the taped corners with scissors. Hand exposure was monitored by handwashing with ivory soap in water. Inhalation monitoring was done in the worker's breathing zone using personal air sampling pumps and octyldecyl silane monitoring tubes.

Biomonitoring was accomplished by measuring acifluorfen residues in total daily urine samples collected by each test subject before, during and after application. Urine volume, specific gravity and creatinine were also measured.

Acifluorfen was quantified in cotton gauze dosimeter pads, detergent wash water, inhalation monitoring tubes and urine using capillary gas chromatography. Acifluorfen Amine Metabolite was quantified in urine using high performance liquid chromatography. The methods were validated by fortifying six replicates of each type of media at four fortification levels which ranged from the LOQ to 5000X LOQ. The average recoveries ranged from 88.1% to 97.6% and the coefficients of variation ranged from 9.7 to 12.6. The recoveries at the lowest level of fortification were similar to the average recoveries. The limits of quantification (LOQ) were 0.1 ug for dosimeter patches and inhalation tubes and 0.1 ug/ml for the 3000 ml handwash and 1200 ml urine samples.

A pilot field fortification test indicated that the average recovery for dosimeters exposed to the sun for <1 hour was 53.2 % and eight hours was 19.5%. The recoveries at the lowest fortification level of 22 ug/2 pads was 0.0%. The average recoveries for the inhalation tubes was

70.2% for 8 hour sun exposure and 75.9% for <1 hour sun exposure because the barrels of the tubes were covered with duct tape. The recoveries at the lowest fortification level of 7.5 ug/tube was similar to the average recoveries. The recoveries for the other media, which were not exposed to the sun, were 86.2% for handwash solution and 90% for urine.

Monitoring media were also fortified in the field and in the lab and were handled in the same manner as samples from the monitored workers with the exception that they had less exposure to the sun (field media was stored in the shade). With the exception of the sun exposed dermal dosimeter pads, the field recoveries were above 60% at all fortification levels. The lab fortification recoveries were above 66% at all fortification levels. Storage stability recovery was above 64% for all media at the longest storage interval of 252 days.

The results were adjusted by the author for the mean recovery of field fortified positive controls. The unit exposure values as shown in Table 5 were calculated by the Agency using the data from this study and Lotus 123. Additional adjustments were made by the Agency to the head and neck dosimeter results to account for low recovery of the sun exposed samples. The overall effect of this adjustment was a dermal unit exposure increase of 20% because the head and neck are only 7% the skin surface area and because only eight out the fifteen replicates had full sun exposures. The other seven replicates had low sun exposures because of cloud cover or closed cab tractors.

The Shapiro and Wilk Test (W-test) indicated that the dermal and inhalation data have a lognormal distribution while the urinary data have a normal distribution. In keeping with the procedures used for PHED exposure analysis, the geometric mean was used for exposure assessment. Default values from PHED Scenario #28 are included for comparison.

Table 5 - Unit Exposure Calculations

	Dermal Exposure (n=15)	Inhalation Exposure (n=15)	Urinary Excretion/Exposure (n=7)
Units	ug/lb ai		[(ug/kg BW)/(ug/kg BW)] *100
Arith Mean	297	2.74	0.63
Geo Mean	185	1.21	0.45
50th Percentile	200	1.07	0.45
95th Percentile	747	9.51	1.6
PHED DATA*	57	1.3	N/A

* PHED Scenario #28 - Liquid/Open Pour/Groundboom/Open Cab (MLAP), Single layer, gloves

The urine sample for one worker was a statistical outlier on day zero and the authors suspected that the sample was contaminated. The urine samples for another worker also showed significant excretion on days -3 and -1 before the study. One worker had an extremely high

dermal exposure because he leaned against the tank during mixing and loading. According to the author, however, this was the worker's normal practice and the samples for this worker were included by the agency in all three of the regression analyses.

The mean percent urinary excretion was 0.63%. The author stated in the study protocol that acifluorfen is excreted in the urine as unchanged parent compound, <1% of the administered dose is retained in the body after oral administration to the rat and dog, and that the major metabolite, which occurs at relatively low concentrations, is the amine derivative of the parent compound. The author also stated that 70% of the systemic dose is excreted in the urine. No references were given for these statements.

The rational for the selection of the inhalation monitoring media was not explained in the study. The media did not have a filter component to capture the aerosol phase of the pesticide spray nor did it include a backup section to measure breakthrough of the vapor phase. Given the low vapor pressure of acifluorfen, it is suspected that airborne acifluorfen would be occur primarily as a mist or aerosol.

After the study, additional testing was done to determine if low recovery of the dermal pads exposed to the sun was due to degradation of acifluorfen by ultraviolet light. It is suspected that the positive control field recoveries reported for dosimeter pads in the study were higher than the sun exposed sample recoveries because the positive controls were covered with a layer of gauze and exposed to partial sun during the replicate while the sample was exposed to full sun. The pilot recovery studies conducted before the study indicated low recoveries of sun exposed dermal pads whereas the bridging studies conducted after the study indicated much higher recoveries. It is suspected that the ultraviolet (UV) intensity during the bridging test conducted in late October was less than the UV intensity during the field tests which were conducted in June and July and the pilot tests which were conducted in May. NOAA UV Index Data for 1998 indicates that the clear sky UV index in Dover, Delaware was 7-9 in May , 8-10 in June/July and 3-4 in October.

The LOD for the urine was listed as 0.01 ug/ml (or 12 ug per typical 1200 ml sample) in the study text but no LODs or LOQs were listed in the individual worker urinary excretion tables. The lowest urinary excretion value in the tables was 0.00016 ug/ml (0.29 ug for the 1080 ml sample) which suggests a limit of detection much less than 0.01 ug/ml. The actual limits of detection could not be determined. This discrepancy affected the unit exposures because many of the urine results reported in the urinary excretion tables were below the LOQs. The LOQ values were substituted by the Agency for the values reported by the author where the values reported by the author were below the LOQ.

Most of the analytical data was the dermal samples was grade A or B except for the sun exposed dosimeter data which was rated grade C for low recovery. An overall PHED grade of ABC/Medium Confidence was assigned to this study. The inhalation data was rated as "low confidence" because the sampling tube did not include a component to capture the aerosol fraction of the herbicide spray. The urine data has severe limitations because the pharmacokinetics of acifluorfen was not well documented, many of the reported results were

below the limit of quantification and there were only seven valid test subjects. For the above reasons, only the dermal and inhalation exposure data were used in this assessment.

PHED Exposure Analysis

In addition to the submitted study, analyses for both private grower and professional short/intermediate term exposures were performed using the Pesticide Handlers Exposure Database (PHED). Five mixer/loader, applicator, mixer/loader/applicator and flagger scenarios were evaluated.

PHED was designed by a task force of representatives from the US EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts – a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates).

Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based upon the central assumption that the magnitude of handler exposures to pesticides are primarily a function of task (e.g., mixing/loading/applying), formulation type (e.g., wettable powders, granulars), application method (e.g., aerial, groundboom), and levels of personal protective clothing worn by the private grower and professional pesticide applicator (e.g., gloves, double layer of clothing).

Once the data for a given exposure scenario have been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (e.g., chest, upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal).

A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure value representing the entire body.

The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The

assessment of data quality is based upon the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Table B1 of Appendix B. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of standard unit exposures for many occupational scenarios that can be used to ensure consistency in exposure assessments.

3.b.iv. Mitigation Summary

Two common risk mitigation approaches used by the Agency are personal protective equipment (PPE) such as chemically-resistant gloves or a double layer of clothing and the use of engineering controls such as closed tractor cabs and closed mixing and loading systems. A tiered approach is used beginning with the baseline mitigation level and, if required, increasing the levels of PPE and engineering controls to achieve an acceptable margin of exposure or cancer risk. Administrative controls are generally not considered as mitigation, because exposure assessments are conducted with respect to the current registered labels. A listing of the mitigation levels is given in Table 6.

Table 6 - Mitigation Levels Using PPE and Engineering Controls.

Mitigation Level	Clothing	Gloves	Respirator
Baseline	Long Sleeve shirt and long pants	None	None
Single Layer PPE	Long Sleeve shirt and long pants, Chemical Goggles, Hat	Chemical Resistant	PF5 Dust Mask
Double Layer PPE	Coveralls over above	Chemical Resistant	PF10 Half Face respirator with OVcartridges and P95 prefilters
Engineering Controls	No PPE is needed because closed systems are used for mixing/loading and closed cabs are used for application.		

Current labels for acifluorfen indicate a variety of PPE use. Most of labels require the minimum use of a long-sleeved shirt, long pants, waterproof gloves, shoes and socks, chemically-resistant headgear for overhead exposure, and protective eyewear. In addition, the Conclude Ultra label specifies the use of coveralls over a short-sleeved shirt and short pants and chemically-resistant gloves (barrier laminate, nitrile rubber, neoprene rubber, viton) and chemically-resistant footwear. The use of both currently-labeled PPE (single layer) and additional PPE has been presented in this risk assessment.

3.b.v. Occupational Handler Risk Assessments

The anticipated use patterns and current labeling indicate several exposure scenarios based upon the types of equipment (e.g., aerial and groundboom) that can potentially be used to make

acifluorfen applications. These scenarios serve as the basis for the quantitative occupational handler non-cancer exposure and risk assessments. The following major occupational exposure scenarios were identified for acifluorfen:

- (1) mixing/loading liquids for aerial application;
- (2) mixing/loading liquids for groundboom application;
- (3) applying spray with fixed-wing aircraft;
- (4) applying spray with a groundboom sprayer;
- (5) mixing/loading/applying liquids for groundboom application; and
- (6) flagging aerial spray applications.

Please note that applications by chemigation systems are prohibited for acifluorfen products (per label instructions). The exposure scenarios for groundboom have been presented from studies in which individuals perform the following tasks: mix/load liquids, apply liquids, and mix/load/apply liquids. The workers in the chemical-specific study (MRID 42361501) did mixing/loading/applying all in the same replicates.

The occupational handler exposure and risk calculations for the above scenarios are presented in the following tables contained in Appendix B:

Table # - Title
B1 - Occupational Handler Exposure Scenario Descriptions for the Use of Acifluorfen
B2 - Numerical Inputs for Occupational Handler Exposure to Acifluorfen
B3 - Baseline PPE Acifluorfen Occupational Exposure and Risk (Non-Cancer)
B4 - Single Layer PPE Acifluorfen Occupational Exposure and Risk (Non-Cancer)
B5 - Baseline PPE Occupational Exposure and Cancer Risk for Acifluorfen
B6 - Single Layer PPE Occupational Exposure and Cancer Risk for Acifluorfen
B7 - Double Layer PPE Occupational Exposure and Cancer Risk for Acifluorfen
B8 - Engineering Control Occupational Exposure and Cancer Risk for Acifluorfen
B9 - Summary of Acifluorfen Occupational Exposure and Risk (Non-Cancer)
B10 - Summary of Acifluorfen Occupational Exposure and Cancer Risk

All equations used in these tables are included at the end of each table. Table B1 also summarizes the data quality of the MRID and PHED exposure data for each exposure scenario using grading criteria established by the PHED Task Force. All calculations were completed using current HED policies pertaining to the completion of occupational and residential exposure/risk assessments (e.g., rounding, exposure factors and acceptable data sources).

3.b.vi. Post Application Worker Exposure Data Sources

The following chemical-specific foliar dislodgeable residue study was submitted by BASF and was judged to be appropriate for use in HED post application exposure/risk assessments.

***EPA MRID 44091101**: Jackson, S. and J. Jordan. (1993) **Foliar Dislodgeable Residues of**

Blazer on Soybeans, Unpublished study prepared by Pan-Agricultural Laboratories, Inc.**;**

*Memorandum: Review of Foliar Dislodgeable Residues of Blazer on Soybeans; dated 2/7/01 by Timothy C. Dole

This study measured dislodgeable foliar residues following groundboom application of acifluorfen - sodium to soybeans to control weeds was submitted by BASF to support the registration of acifluorfen-sodium. The formulation used was Blazer Herbicide, which is a soluble concentrate that contains 2 lb/gallon acifluorfen-sodium. This study was conducted at three sites located on farms in Indiana (IN), Mississippi (MS) and Georgia (GA). A wetting agent was also used during application. Two applications, 15 days apart, were made at each site. The target rates for the application were 0.125 and 0.375 lb/ai/acre to yield a total application of 0.5 lb ai/acre which is the maximum label rate per year. The finish spray was applied to the test sites using tractor mounted boom sprayers. Two plots were established at each site, one treated and one untreated. The treated plot was divided into three subplots and the untreated into two subplots. The subplots were further divided into ten mini-plots for sampling.

Three samples at each site were collected before and after each application then approximately 1,3,5,7,10,14,21,28 and 35 days after the second application. Four soybean leaf disks were collected using 2.5 cm Birkestrand leaf punches from each of the ten miniplots to make the 40 disk sample which had a total surface area of 393 cm^2. Residues were dislodged in 100 ml of a 0.05% ivory soap solution using a reciprocal shaker at 200-250 cpm for ten minutes. Field spikes were prepared by collecting and dislodging leaf disks from the untreated plots in the same manner as the samples collected from the treated plots. Separate Birkestrand punches were used for the treated and untreated samples at each site.

Dislodgeable foliar samples were analyzed using a specific BASF Method that involves Gas Chromatography with electron capture of the acifluorfen ester and HPLC of the Acifluorfen Amine. The method was included in the study report. The LOD in terms of leaf area is 0.0051 ug/cm^2 and LOQ is 0.012 ug/cm^2. This method was validated by analyzing three replicates of acifluorfen sodium or acifluorfen amine at spike levels of 0.013, 0.056, 0.51 and 5.1 ug/cm^2. The average recovery for acifluorfen sodium was 96% with a coefficient of variation of 9.9. The average recovery for acifluorfen amine was 81.8% with a coefficient of variation of 4.6. The recoveries for the concurrent laboratory recovery acifluorfen samples averaged 99.3% +/- 9.6% (n=60). The recoveries for the acifluorfen-amine analyses averaged 92.9% +/- 15.6% (n=56). Fortifications ranged from the LOQ of 0.012 ug/cm^2 to 5.1 ug/cm^2.

No acifluorfen sodium residue was detected prior to either the first or second application at any of the sites. The average acifluorfen sodium DFR (n=3) on day zero after the second application was 0.68 ug/cm^2 in IN, 0.74 ug/cm^2 in MS and 0.25 ug/cm^2 in GA. The DFR declined to the LOQ by day 1 at the GA site, day 3 at the MS site and day 9 at the IN site. Regression analysis of the natural logarithms of the first 6 data points for the IN site yielded an R value of 0.96 and a half life of 1.4 days. Regression analysis of the three MS data points yielded

an R value of 0.99 and a half life of 0.45 days. The slope for the two GA data points yielded a half life of 0.29 days. The DFR level for acifluorfen amine was <0.013 ug/cm^2 at all of the sites on day zero following the first and second applications.

3.b.vii. Post-Application Worker Risk Assessments

The Agency has determined that workers may be exposed to acifluorfen during scouting, hand weeding and irrigating of fields which have been previously treated with acifluorfen. Due to the frequency and duration of these exposures coupled with the rapid dissipation of acifluorfen following applications, it was determined that these exposures would be short-term and intermediate-term in duration and would occur primarily through the dermal route. Potential inhalation exposures are not anticipated for post-application worker exposures, and the Agency currently has no policy/method for evaluating non-dietary ingestion by workers due to poor hygiene practices or smoking. As a result, only dermal exposures were evaluated in the post-application worker assessment. The Agency anticipates that all harvesting of peanuts, rice and soybeans will be performed mechanically and that the residues will have dissipated.

A restricted entry interval (REI) is defined as the duration of time which must elapse before residues decline to a level so entry into a previously treated area and engaging in a specific task or activity would not result in exposures which exceed the Agency's level of concern. Equations were previously described in Section 3.b.i.

Transfer coefficients are a measure of the relationship between exposure to dislodgeable foliar residues (DFRs) and exposure level measured while engaged in a specific activity or job function (e.g., scouting or irrigating). Transfer coefficients are used to estimate potential human exposure. The values assigned by the Science Advisory Council on Exposure for dermal transfer coefficients represent estimates of potential exposure contact during specified tasks. These standard transfer coefficients will be in use until the Agriculture Re-entry Task Force (ARTF) provides the Agency activity-specific transfer coefficients. Table 7 summarizes the standard transfer coefficients and activities along with the specific crops and application rates addressed in the post-application worker assessment.

Table 7. Post-Application Potential Dermal Transfer Coefficients

Transfer Coefficient Group	Activities	Transfer Coefficient (cm^2/hr)*	Foliage Development	Comments
Field/row crops, low/medium (includes soybeans rice and peanuts)	Hand Weeding	100	Full	Central value from MRID 426891 - hoeing in cotton and beans.

Field/row crops, low/medium (includes soybeans rice and peanuts)	Irrigate and Scout	1500	Full	Central value from MRID 426891 - hoeing in cotton and beans.

* Standard values for transfer coefficients are from HED Exposure Science Advisory Council (SAC) Policy #3.1 dated August 7, 2000.

Estimated occupational exposures and cancer risks for scouting and irrigating peanuts, rice and soybeans were calculated. The equations used in these calculations and the results are presented in the following tables and spreadsheets contained in Appendix C:

Table # - Description
Table C1 - Summary of Estimated Occupational Post-Application Cancer Risks for Acifluorfen
Spreadsheet C2 - Acifluorfen Risks Based Upon Indiana DFR Data (0.125 lb ai/acre)
Spreadsheet C3 - Acifluorfen Risks Based Upon Indiana DFR Data (0.375 lb ai/acre)
Spreadsheet C4 - Acifluorfen Risks Based Upon Mississippi DFR Data (0.125 lb ai/acre)
Spreadsheet C5 - Acifluorfen Risks Based Upon Mississippi DFR Data (0.375 lb ai/acre)

3.b.viii. Residential Applicator Risk Assessments

HED has determined from residential use patterns and current labeling that residential pesticide applicators are likely to be exposed during acifluorfen use as a spot treatment to kill weeds and that this use would result in short-term exposures. This scenario will serve as the basis for the quantitative exposure and risk assessments:

- (1) applying by aerosol can (surrogate scenario for RTU spray treatment).

Specific PHED data were unavailable for this residential applicator scenario, so similar PHED data were used as surrogate data in the assessment. This scenario is described in Table D4 of Appendix D and involves the application of pesticide from an aerosol can to treat kitchen baseboards. The residential pesticide applicator exposure and risk calculations are presented in the tables contained in Appendix D. All of the equations used in these tables are summarized at the end of the tables and in *Section 3.b.i* of this document.

Table D4 of Appendix D summarizes the parameters and caveats specific to the PHED exposure data used for the exposure scenario. These caveats include a description the data source and quality. Generally, the assessment of the data is based upon the number of observations and the available quality control data. Quality control data are assessed based upon a grading criteria established by the PHED Task Force.

It is also important to note that residential PHED values represent an applicator wearing typical residential clothing of short-sleeved shirt, short pants and no gloves. Homeowner uses are not covered by the Worker Protection Standard. The Agency does not have the legal authority to require the use of PPE and/or engineering controls for residential applicators, therefore, the use of PPE and/or engineering controls is not considered in the residential applicator risk assessment.

3.c. Occupational and Residential Risk Characterization

The occupational and residential non-cancer and cancer risk assessments are summarized herein. Please refer to the appropriate tables as stated in the text. These tables are the basis for the risk assessments.

3.c.i. General Risk Characterization Considerations

Several issues must be considered when interpreting the results of this exposure assessment. These include:

- Measured and estimated exposures occurred primarily by the dermal route. The inhalation exposures typically accounted for only 1-5 % of the total exposure.
- Private growers are defined as persons who apply acifluorfen, irrigate and scout only single farms.
- Professional handlers or workers are defined as persons who apply acifluorfen, irrigate and scout multiple farms.
- Chemical-specific transfer coefficients were not available for this risk assessment.

3.c.ii. Occupational Handler Risk Characterization

Non-Cancer Results

The calculations of private grower and professional acifluorfen handlers' combined dermal and inhalation risks indicate that two exposure scenarios are below 100 at the baseline level and exceed HED's level of concern. These scenarios are the mixing and loading of liquids for aerial and groundboom applications. All of the remaining exposure scenarios at the baseline and higher levels of mitigation are above 100 and do not exceed the Agency's level of concern. Table 8 summarizes the ranges of combined MOEs for the various exposure scenarios.

Table 8. Non-Cancer Combined MOEs for Occupational Exposure to Acifluorfen

Non-Cancer MOEs	Baseline	Single Layer PPE	Double Layer PPE	Engineering Controls
Combined MOE Range	4.6 - 27,000	420 - 32,000	N/A	N/A

A brief summary of the specific exposure scenarios which exceeded the Agency's level of concern (i.e. combined MOEs less than 100) is presented below. Please refer to Table B9 of Appendix B for a more detailed summary of the combined MOEs for each exposure scenario.

Baseline Exposure Scenarios with Combined MOEs less than 100

(1) mix/load liquids for aerial application at all application rates.
(2) mix/load liquids for groundboom application at the higher application rates

Single Layer PPE Scenarios with Combined MOEs less than 100

None.

Private grower and/or Professional Pesticide Applicator Scenarios of Concern

The calculations of private grower and professional acifluorfen applicators' combined dermal and inhalation risks indicate that, at the single layer PPE level or above, all of the scenarios have combined MOEs above 100. Therefore, there are no non-cancer exposure scenarios of concern for private grower and professional acifluorfen applicators.

Data Gaps for Private Grower and Professional Pesticide Applicator Scenarios

There are no data gaps for the exposure scenarios presented in this assessment. However, the Agency requires additional information regarding chemical-specific use information for acifluorfen which establishes if one individual performs mixing/loading/applying tasks for groundboom applications or if more than one individual performs these tasks. It is critical that the Agency obtain chemical-specific use information for both individual and professional pesticide applicators.

Cancer Results

The cancer risk calculations for private grower and professional acifluorfen handlers and applicators indicate that two exposure scenarios exceed 1.0×10^{-4} at the baseline level. These scenarios are the mixing and loading of liquids for aerial and groundboom applications. All of the remaining exposure scenarios at the baseline and higher mitigation levels do not exceed 1.0×10^{-4}. However, several scenarios exceed 1.0×10^{-6} and 1.0×10^{-5} at various levels of mitigation. None of the private grower pesticide applicator scenarios exceed 1.0×10^{-6} for the engineering controls level. One of the professional pesticide applicator scenarios (mixing/loading for aerial application) exceeds 1.0×10^{-6} even when accounting for the use of engineering controls. Table 9 summarizes the cancer risks for private grower and professional applicators.

Table 9. Cancer Risks for Private Grower and Professional Handlers and Applicators

Cancer Risk	Baseline	Single Layer PPE	Double Layer PPE	Engineering Controls
Private grower	$1.5\text{x}10^{-7}$ to $1.1\text{x}10^{-4}$	$1.2\text{x}10^{-7}$ to $1.6\text{x}10^{-6}$	$9.7\text{x}10^{-8}$ to $6.4\text{x}10^{-7}$	$9.3\text{x}10^{-9}$ to $3.3\text{x}10^{-7}$
Professional	$4.3\text{x}10^{-7}$ to $1.1\text{x}10^{-3}$	$1.2\text{x}10^{-6}$ to $1.6\text{x}10^{-5}$	$9.7\text{x}10^{-7}$ to $6.4\text{x}10^{-6}$	$9.3\text{x}10^{-9}$ to $3.3\text{x}10^{-7}$

A brief summary of the specific exposure scenarios which exceeded the Agency's level of concern (i.e. cancer risk greater than 1.0×10^{-4}) is presented below. A more detailed summary is provided in Table B10 of Appendix B.

Baseline Exposure Scenarios with cancer risk greater than 1.0×10^{-4} (Private grower)

(1) mixing/loading liquids for aerial application (1.1×10^{-4})

Baseline Exposure Scenarios with cancer risk greater than 1.0×10^{-4} (Professional)

(1) mixing/loading liquids for aerial application (1.1×10^{-3})
(2) mixing/loading liquids for groundboom application (2.4×10^{-4})

Single Layer PPE Scenarios with cancer risk greater than 1.0×10^{-4} (Private and Professional)

None.

Double Layer PPE Scenarios with cancer risk greater than 1.0×10^{-4} (Private and Professional)

None.

Engineering Control Scenarios with cancer risk greater than 1.0×10^{-4} (Private and Professional)

None.

Private grower and/or Professional Applicator Scenarios of Concern

The calculations of cancer risks indicate that, at the highest level of mitigation available and/or feasible for a specific scenario, all of the scenarios have cancer risks less than 1.0×10^{-4} for both private grower and professional handlers/applicators. Therefore, there are no cancer exposure scenarios of concern for these scenarios.

3.c.iii. Post-Application Worker Risk Characterization

Non-Cancer Results

Table 10 summarizes the estimated MOEs for workers scouting weeds and irrigating peanuts, rice and soybeans. The calculations indicate that the MOEs are greater than 100 on day zero for both private growers and professional workers. It should be noted that the MOEs are the same for private growers and professional workers because the MOEs are based upon a short term endpoint and are not affected by the number of exposure days. The current REI for acifluorfen is 48 hours based on acute eye irritation (toxicity category I). The calculated REI is zero.

Table 10. Estimated Acifluorfen Post-Application Exposures and Risks (Non-Cancer)				
Exposed Person	**Application Rate (lb ai/A)**	**Transfer Coefficient (cm^2/hr)[a]**	**Activities**	**MOE on Day 0***
Based Upon DFR Data for Indiana (MRID 440911-01)				
Private Grower or Professional Worker	0.125	1500	Irrigate and Scout - Medium Exposure	1300
	0.375	1500	Irrigate and Scout -Medium Exposure	740
Based Upon DFR Data for Mississippi (MRID 440911-01)				
Private Grower or Professional Worker	0.125	1500	Irrigate and Scout - Medium Exposure	1800
	0.375	1500	Irrigate and Scout - Medium Exposure	670

* The MOEs on day zero are greater than 100, therefore, an REI is not required for non-cancer risks

Cancer Results

Table 11 summarizes the private grower and professional worker post-application cancer risks for scouting and irrigating soybeans, peanuts and rice treated with Acifluorfen. None of the post-application cancer risks exceed 1.0×10^{-4} for day 0 exposures.

Table 11. Estimated Post-Application Cancer Risks.				
Exposed Person	**Application Rate (lbs ai/acre)**	**Annual # Days Irrigation and Scouting**	**Cancer Risk on Day of Application (Day 0)**	**Day on which Cancer Risk is less than 1×10^{-6}**
Using Indiana DFR Data from MRID 440911-01.				
Private Owner Professional	0.125	2 20	1.9×10^{-6} 1.9×10^{-5}	2 6
Private Owner Professional	0.375	2 20	3.4×10^{-6} 3.4×10^{-5}	3 8
Using Mississippi DFR data from MRID 440911-01.				
Private Owner Professional	0.125	2 20	1.4×10^{-6} 1.4×10^{-5}	1 2
Private Owner Professional	0.375	2 20	3.7×10^{-6} 3.7×10^{-5}	1 3

3.c.iv. Residential Applicator Risk Characterization

The residential exposure scenario yielded a combined MOE of 7400 while the target MOE is 1000 due to the FQPA safety factor for females 13-50 years of age. In addition, a cancer risk of 8.4×10^{-7} was calculated for this scenario which is below HED's level of concern ($1.0 \times 10^{-6)}$ for the general population.

The following exposure facts and assumptions were made for the cancer risk assessment:

1) The residential acifluorfen products contain 0.12% acifluorfen.
2) Container sizes range from 24 ounces to one gallon and include a quick connect sprayer.
2) Residential applicators would make 2 spot treatment applications of acifluorfen in one year,
3) Each spot treatment application would use half a gallon of acifluorfen product;
4) Residential applicators may have 50 years of potential exposure over a 70 year lifespan.

It should be noted that cancer risk is calculated on an annual basis and does not depend upon the amount used in any one day. These calculations indicate that cancer risks will not exceed 1.0×10^{-6} if amount used per year does not exceed one gallon.

3.d. Incident Reports

The incident report was developed under a separate memo by Monica Spann, M.P.H. through Jerome Blondell, PhD. of the Office of Pesticide Programs (DP Barcode #264815 of 4/6/00). No information is available on incidents related to the use of sodium acifluorfen from any of the available data sources consulted by the Health Effects Division. Little or no usage has been reported for this pesticide, either in surveys of home use or agricultural use in California. In addition, on the list of the top 200 chemicals for which NPTN received calls from 1984-1991 inclusively, sodium acifluorfen was not reported to be involved in human incidents.

3.e. Information and Data Needs

Several areas of the risk assessment and characterization would improve with more information and data. Areas of information and data needs include:

- The agency requests additional dermal absorption data to refine the dermal absorption factor of 20% which was derived from a 1986 rat study. This study indicated that 1 to 43.5% of the applied dose remained on the skin following a ten hour exposure period and subsequent washing with distilled water.
- The agency requests additional pharmacokinetic data to interpret the biomonitoring study.
- The Agency requests exposure data for the residential use because there is no PHED or literature data for application with a trigger sprayer.